

REMARKS

§112, First Paragraph Rejection:

Enablement

Claims 1-4 have been rejected solely under 35 U.S.C. §112, first paragraph, for lack of enablement. (Paper No. 20070801 at 2). In making the rejection, the Examiner acknowledged that the specification is “enabling for a specific L-sorbosone dehydrogenase” (*Id.*).

The Examiner, however, asserted that “[t]he specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims whereby the structure of the specific L-sorbosone or the specific sequence is required *in view of the fact that the prior art is within the scope of the claim enzyme as evidenced by US 6,242,233 which properties are within the scope of the claimed properties.*” (*Id.*) (emphasis added).

The Examiner further asserted that “Applicant is required to submit claimed subject matter that differentiates between the prior art, which overlaps the instant claims *due to differences between the two enzymes*” and “[i]f Applicant does not submit inherent limitations supported by the instant specification, this Examiner will consider that the instant specification is fatally defective *lacking suitable enabling differences* for the claimed enzyme over the prior art.” (*Id.*) (emphasis added).

Initially we note, it is the Examiner’s burden to demonstrate that a specification is not sufficiently enabling. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). To carry his/her burden, the Examiner must identify and clearly articulate the

factual bases and supporting evidence that allegedly establish that undue experimentation would be required to carry out the claimed invention. *Id.* at 370. It is well established that claims must be separately analyzed. *Ex parte Jochim*, 11 USPQ2d 561 (BPAI 1988).

The rejection, however, completely fails to identify or articulate any factual basis or supporting evidence to establish that undue experimentation is required to practice the invention. The Examiner asserted only that “[t]he specification does not enable any person skilled in the art to which it pertains ... ***in view of the fact that the prior art is within the scope of the claim enzyme as evidenced by US 6,242,233 which properties are within the scope of the claimed properties.***” (Paper No. 20070801 at 2) (emphasis added). The Examiner’s observation, however, falls short. The Examiner failed to present any evidence or reasoning why this observation is relevant to enablement. There is no evaluation of what one skilled in this art would have understood from what is disclosed in the Specification. Moreover, there is no attempt to even define what the level of skill in the art was. At bottom, the Examiner’s observation, without more, is an impermissible attempt to shift the burden to the Applicant to positively establish enablement.

As is well known, burden-shifting of this kind is not allowed. “In order to make a rejection, ***the examiner has the initial burden*** to establish a reasonable basis to question the enablement provided for the claimed invention.... ***[T]he minimal requirement is for the examiner to give reasons*** for the uncertainty of the enablement. ***This standard is applicable even when there is no evidence in the record of operability without undue experimentation beyond the disclosed***

embodiments." MPEP § 2164.04 (8th ed. Rev. 5, August 2006, p. 2100-191) (emphasis added). The Examiner's conclusion that "the instant specification is fatally defective ***lacking suitable enabling differences*** for the claimed enzyme over the prior art" fails to satisfy the Examiner's burden and is ***simply*** not the correct legal standard. (Paper No. 20070801 at 2) (emphasis added). Thus, the rejection falls short of the kind of analysis and evidence required to establish a *prima facie* case for lack of enablement. For this reason alone, the rejection should be withdrawn.

Moreover, the Examiner has misinterpreted the scope of the claims by failing to recognize that the enzyme disclosed in U.S. Patent No. 6,242,233 (aldehyde dehydrogenase) cited by the Examiner is the ***same enzyme*** recited in the currently claimed process (L-sorbose dehydrogenase). (See Specification at page 1, lines 1-28). The Examiner's statement that "Applicant is required to submit claimed subject matter that differentiates between the prior art, which overlaps the instant claims ***due to differences between the two enzymes***" is factually ***wrong*** and further undermines the rejection. (Paper No. 20070801 at 2) (emphasis added).

Thus, because the Examiner misinterpreted the scope of the claims, the rejection must be withdrawn for this additional reason. The MPEP commands it.

Before any analysis of enablement can occur, it is necessary for the examiner to construe the claims. For terms that are not well-known in the art, or for terms that could have more than one meaning, it is necessary that the examiner select the definition that he/she intends to use when examining the application, based on his/her understanding of what applicant intends it to mean, and explicitly set forth the meaning of the term and the scope of the claim when writing an Office action. MPEP § 2164.04 (8th Ed., Rev. 5, Aug. 2006, p. 2100-191) *citing Genentech v. Wellcome*

Foundation, 29 F.3d 1555, 1563-64, 31 USPQ2d 1161, 1167-68 (Fed. Cir. 1994).

And, the Board's own decisions demand it. *Ex parte Kosley*, 2002 WL 130548, *5-7 (BPAI 2002) (unpublished) (reversing an examiner's enablement rejection because the examiner improperly construed appellants' claims); *Ex parte Schoemaker*, 2003 WL 21280014, *3-4 (BPAI 2003) (unpublished) (stating "the examiner erred in construing the claims" and reversing "the rejection for non-enablement because the specification is presumed to be enabling and the examiner has not presented sufficient evidence or scientific reasoning to support a conclusion to the contrary"); *Ex parte Miles*, 2004 WL 318773, *4 (BPAI 2004) (unpublished) (vacating examiner's rejections under 35 U.S.C. § 112, first and second paragraphs, and "encourag[ing] the examiner to take a step back and construe the claimed invention as a person of ordinary skill in the art, using appellants' specification as a guide. After, having the opportunity to properly construe the claimed invention the examiner will be in a better position to determine whether appellants' specification enables the full scope of appellants' claimed invention."); and *Ex Parte Tsunoda*, 2002 WL 31257863, *3 (BPAI 2002) (unpublished) (rejection reversed because examiner misconstrued the appealed independent claim).

We further note that even a "considerable amount" of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance. MPEP § 2164.05 and *In re Wands*, 8 USPQ at 1404. Indeed, it is well recognized that "a patent need not teach, and preferably omits, what is well known in the art." MPEP § 2164.01 (8th ed. Rev. 5, August 2006, p. 2100-187) citing *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc.*

v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Here, the Specification contains **three** detailed examples and **three** tables that include detailed descriptions of embodiments of the claimed process. In particular, the Specification describes how to prepare and use the claimed L-sorbose dehydrogenase enzyme in the currently claimed process to produce vitamin C. (See Specification at page 5, line 1 to page 8, line 22). Thus, one skilled in the art would recognize how to produce vitamin C from L-sorbose utilizing the enzyme L-sorbose dehydrogenase in the claimed process. Nothing more is required.

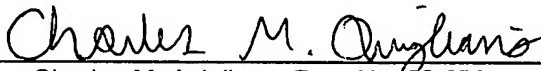
In sum, the specification and knowledge in the art provide ample guidance to allow one of skill in the art to practice the claimed invention without undue experimentation. Accordingly, the rejection is factually insufficient to support a rejection for lack of enablement, and for this reason also, the rejection should be withdrawn.

For the reasons set forth above, it is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

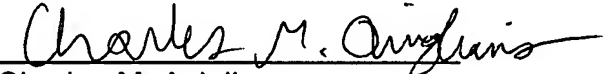
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Accordingly, for the reasons set forth above, withdrawal of the rejection and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 1, 2007.


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Respectfully submitted,

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